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UNITED STATES DISTRICT COURT

DISTRICT OF ARIZONA

In Re Bard IVC Filters Products Liability Litigation	No. MD-15-02641-PHX-DGC **PLAINTIFFS' RESPONSE TO DEFENDANTS' MOTION TO EXCLUDE THE OPINIONS OF REBECCA BETENSKY, PH.D.**

Plaintiffs oppose Defendants' Motion to Exclude the Opinions of Rebecca Betensky, Ph.D. ("Motion" or "Mot.") [Doc. 7288]. Plaintiffs incorporate in this response their Omnibus Statement of Law and Generally-Applicable Arguments in Opposition to Bard's Motions to Exclude Plaintiffs' Experts under Rule 702 and *Daubert* ("Omnibus Mem.") [Doc. 7799], filed contemporaneously herewith. For the reasons set forth herein and in the Omnibus Memorandum, this Court should deny the Motion.

I. INTRODUCTION

Bard's challenge to the reliability of Dr. Betensky's analysis (of adverse event reporting rates for Bard's retrievable filters compared to the 1995 Simon Nitinol Filter (SNF)) should be denied. Dr. Betensky considered all available data and used an accepted method for her analysis which is relevant to the issues in the case, will be helpful to the jury, and can be relied on by experts with clinical training who can properly interpret the results.

The best indicia of reliability of an expert's methodology is whether it is deemed reliable outside of the courtroom. *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 152 (1999). Here the answer is yes. The type of analysis at issue was also conducted *by Bard* to evaluate its filters, is routinely performed and relied on by device manufacturers and physicians, and can be found in peer-reviewed, published studies.

Dr. Betensky's analysis provides relevant evidence of a safety signal, plus independent and confirming evidence that Bard's claim of "substantial equivalence" was not supported by reliable evidence. Contrary to Bard's assertion that Dr. Betensky relied on MAUDE data (Mot. at 4, 5, 8, 12, 15), Dr. Betensky actually evaluated *Bard's own sales figures* combined with adverse event reports *that Bard extracted* from MAUDE, and then *compiled and vetted*. (Ex. 1; Betensky Rpt., Jan. 27, 2017.) Dr. Betensky compared these data for multiple Bard retrievable filters against data for the 1995 SNF—the predicate device for the Bard Recovery filter—among multiple time-periods and several different adverse event types. The reliability of Dr. Betensky's work was enhanced because she performed sensitivity analyses, a review of the data to correct errors made by Bard when it made similar comparisons, (*e.g., id.* at 1, 4, 11, 12), and two additional analyses—neither of which Bard challenges, and both of which are consistent with her adverse event reporting rate analysis.[1]

Dr. Betensky concluded that for most time-periods and most adverse events considered, there was [redacted].[2] (*Id.*) Based on her analysis that the differences in adverse event

[1] The opinions not challenged by Bard include 1) a statistical analysis of a bench test comparing Recovery and SNF migration resistance, showing that the Recovery filter migrated with less pressure than the SNF (Ex. 1, at 15-16); and 2) an analysis of Bard's estimates of how often various adverse events would occur, concluding that Bard predicted that its later devices would fail more often than its earlier ones. (Ex. 2, Betensky Rept. Mar. 3, 2017).

[2] For some adverse events, the discrepancy in reporting rates was over 500%. For Recovery filter versus SNF migration events through July 2010, the disparity was *over 2500%.*

reporting rates was so large, and after considering potential limitations, (Ex. 1, pp. 11-14), Dr. Betensky concluded that it is likely that [redacted] (Mot. at 7, 10.) This opinion was based on an analysis of the data, with the conclusion that: [redacted] (Ex. 1., p. 11.)

Bard's challenge to this opinion should be rejected because *Bard repeatedly made these same comparisons* prior to this litigation and in the ordinary course of business.[3] Dr. Betensky made these comparisons because the 1995 version of the SNF was the predicate to the Recovery filter, so the Recovery and each subsequent filter was based on the SNF and Bard claimed, per FDA regulation, that they were all substantially equivalent. (Ex. 6, p. 10.)

Dr. Betensky's conclusion that it was likely [redacted] is based on a standard application of statistical techniques and careful analysis of the available data. She concluded: [redacted] This analysis adds to and is consistent with the other evidence, because the large adverse event reporting discrepancies likely represent a true difference in the rate of failures.

[3] *See, e.g.*, Ex. 3 (Bard's assessment that reporting rate of perforation, migration, fracture, and death for Recovery filter was over 400% more often than "all other filters."); Ex. 4, at 36 (Bard chart showing [redacted]); Ex. 5 (Email from Bard VP asking [redacted])

II. ARGUMENT

Bard's motion should be denied for three reasons. First, the challenged analyses are based on accepted methods that Bard, the FDA, and other scientists use. Second, Dr. Betensky's opinions mirror the analysis conducted by Bard's consultant that Bard clawed-back as alleged "work-product." Bard specifically argued that Plaintiffs' experts could redo this work, which is exactly what Dr. Betensky has done. Bard should not now be permitted to exclude the very analysis it claimed was available to Plaintiffs in justifying its own internal analysis as privileged from discovery. Third, Bard's challenge to the time periods Dr. Betensky used for her comparisons should be rejected because it would have required her to analyze data for SNF that Bard refused to produce and is based on speculation that is demonstrably untrue.

A. Dr. Betensky used an accepted method that was used by Bard, is recommend by the FDA, and is used in peer-reviewed literature.

Dr. Betensky's opinions are based on accepted methods[4] as demonstrated by the fact that 1) Bard itself not only uses these same data, but has confirmed through documents and testimony that it is reliable; 2) the FDA recommends that manufacturers use this information to conduct this type of analysis; 3) doctors making treatment decisions have published similar analyses of IVC filters;[5] 4) case law supports admission of this evidence; and 5) multiple lines of evidence support Dr. Betensky's opinion and

[4] Bard does not challenge Dr. Betensky's qualifications as to her statistical analysis; indeed she is eminently qualified to offer biostatistical opinions. She is the Director of the Biostatistics Program for the Clinical and Translational Science Center at Harvard University and of the Biostatistics Core for the Alzheimer's Research Center at Massachusetts General Hospital. She is also the Director of the neurostatistics and neuro-epidemiology training program at Harvard School of Public Health. She is a faculty member at the Harvard-MIT Division of Health Sciences and Technology. She has taught courses in biostatistics at the Harvard School of Public Health and has authored or co-authored 204 peer-reviewed articles relating to biostatistics.

[5] That treating physicians rely on this type of analysis makes it particularly pertinent to a failure-to-warn case where Plaintiff will show that Plaintiff's doctors would have avoided the injuries claimed if they had this information.

conclusions, which cannot be taken in isolation and render her overall opinion more reliable.

1. The data Dr. Betensky used were reliable as confirmed by Bard.

Dr. Betensky did not use MAUDE data as Bard claims. Instead, she relied on *Bard's* internal adverse event *and sales* data from more than 15 Bard datasheets, which Bard's witnesses conceded were "complete and accurate," "verified," and "reliable,"[6] and "consistent with actual failure rates." (Ex. 12 at 313:17-19 (testimony of Bard Peripheral Vascular President John McDermott).) Thus, any argument that MAUDE data are unreliable is not applicable to Dr. Betensky's analysis.

While Bard's adverse event data served as numerators for each time-period and adverse event of interest, Dr. Betensky (like Bard) derived denominators from Bard's sales data. Dr. Betensky followed standard, reliable, statistical methods, including multiple "sensitivity analyses," as she testified in her deposition.[7] She also confirmed (as did Bard), that the results of the statistical analysis were consistent with filter bench test results. (Ex. 9 at 84:11-19, 89:5-23.)

Bard claims there are limitations to comparing SNF adverse event reporting rates against those of retrievable filters. While interpreting these results requires consideration of any potential limitations, Dr. Betensky did indeed identify, consider, and interpret her results in light of such potential limitations. She concluded that the extremely large magnitude of the disparities in adverse event reporting rates between SNF and the other

[6] Ex. 7 at 156:8-9; Ex. 8 at 114:6-116:2 (comparisons between Bard products were reliable, and more reliable than MAUDE). Bard's Motion omits the important fact that Dr. Betensky relied on data accumulated and verified *by Bard*. Dr. Betensky testified: "Q. So your opinions in this case are not based in any way on MAUDE data that you've extracted from the database yourself? A. I have not extracted the data myself. I trusted that the company's extractions of the data were a good, reliable source." (Ex. 9 at 16:16-21.) Bard documents further confirm with respect to the spreadsheets Dr. Betensky relied on that "the accuracy of the data was verified" by Bard and "discussed with the independent consultant." (Ex. 10, p. 7.) Bard used multiple personnel "to ensure that the [adverse event data] is complete and accurate." (Ex. 11 at 92:5-94:16.)

[7] A sensitivity analysis is "a method [used by biostatisticians] . . . to test the reliability of some kinds of calculation or comparison." (Ex. 9, at 84:1-10.)

filters indicated that there were more complications reported for the later filters. *Id.* at 61:5-8, 101:18-111:22.[8] All scientific studies have limitations, and when an expert identifies and considers limitations, it does not diminish the reliability of the expert's opinion, it strengthens it.

Daubert does not require scientific evidence to be without flaws and limitations. *In re Phenylpropanolamine (PPA) Prods. Liab. Litig.*, 289 F. Supp. 2d 1230, 1240 (W.D. Wash. 2003) ("Scientific studies almost invariably contain flaws") (quoting *Reference Manual* and criticizing defendant's "ex post facto dissection" of study); *In re Orthopedic Bone Screw Prods. Liab. Litig.*, 1997 WL 230818, at *8 (E.D. Pa. May 5, 1997) (holding that despite potential for biases in study that "may . . . render its conclusions inaccurate," study was sufficiently reliable to be admissible); Federal Judicial Center, *Reference Manual on Scientific Evidence* 337 (2d ed. 2000) ("It is important to recognize that most studies have flaws. Some flaws are inevitable given the limits of technology and resources."); Gastwirth, *Reference Guide on Survey Research*, 36 Jurimetrics J. 181, 185 (1996) (review essay) ("One can always point to a potential flaw in a statistical analysis.").

Moreover, in the normal course of business, Bard used a similar method for comparing adverse event rates and sales data. (Ex. 16-22; *see also* n.3, *supra.*) Bard also used analyses of its adverse event data to defend its product to the medical community and public. (Ex. 23) (representing that "there is no significant difference in the rates of (migration) complications between competitive devices, including Recovery"). (Ex. 23 at 922.) Elsewhere, Bard endorsed use of adverse event data, by telling doctors that the "only way" to compare migration rates for different filters was "to review the number of reported incidents to the FDA MAUDE database." (Ex. 24.) The evidence will show that

[8] Bard's claim that Dr. Betensky lacks the expertise to evaluate potential limitations is without merit. She considered the potential limitations by evaluating trends in the data as a biostatistician, Ex. 1, pp. 11-14, while experts who relied on her report evaluated it using their clinical expertise. *E.g.*, Ex. 13, ¶ 314; Ex. 14, ¶ 111; Ex. 15, ¶ 33.

Bard's disclosures to doctors of its comparative analyses were false and misleading; Dr. Betensky's analysis is also relevant for this purpose.

2. The FDA recommends comparison of reporting rates and Bard's own biostatistician agreed with this recommendation.

As noted above, Dr. Betensky did not use MAUDE data—she used Bard's adverse event data which had been compiled, reviewed, vetted, and verified by Bard, and thus are more reliable. There is, however, an obvious relationship between the MAUDE data and Bard's data, so the FDA's position on the appropriate use of MAUDE may be of interest to the Court. In referencing relevant FDA guidelines, Bard omitted the full FDA position, which is that the adverse event data *should* be used to calculate adverse event reporting rates:

> Although we recognize these limitations, we recommend that sponsors calculate crude adverse event reporting rates as a valuable step in the investigation and assessment of adverse events. . . . Comparisons of reporting rates and their temporal trends can be valuable, particularly across similar products or across different product classes prescribed for the same indication.[9]

(Ex. 25, 2005 FDA Guidance.) Bard's own biostatistics expert testified that this guidance document is good advice for device manufacturers, (Ex. 26, at 168:8-169:6), and its regulatory expert supports the use of adverse event analyses for regulatory decisions, (Ex. 27, at 69:9-14; 71:18-72:23; 79:16-80:1).

Analytically, this type of analysis applies with even more force to adverse event reports pertaining to medical devices because the causal relation is apparent. This is particularly true with IVC filters where migration, fracture, tilt, and penetration can be visualized using imaging.

3. Reporting rates are used in peer reviewed literature.

Scientists and physicians outside the litigation setting have used and analyzed MAUDE data to assess risk and to compare medical device safety records, and have

[9] Implicit in the FDA statement is the premise that calculation of an adverse event reporting *rate* requires both a numerator (adverse event reports) and a denominator (sales). Both Bard and Dr. Betensky, used sales data for the denominator. Nowhere does the FDA advise against using MAUDE *with a denominator* to calculate adverse event reporting rate.

published those results in the peer reviewed medical literature. Notably, two independent medical research teams used and analyzed MAUDE adverse event data for IVC filter complications (including Bard's filters) in two published studies.[10] Thus, outside of the courtroom, MAUDE data are deemed sufficiently reliable that scientists and physicians are using it to understand safety profiles and comparative complication rates of medical devices.

Doctors and hospitals also use the MAUDE database to evaluate the safety of medical products. For example, [redacted]. (Ex. 28 at 244:22-245:7.) As noted by Dr. Betensky in her rebuttal report (Ex. 31 n.5), multiple other researchers used MAUDE data to assess safety of other medical devices and published their results in the peer reviewed medical literature.[11] The fact that these data are sufficiently reliable for epidemiologists and physicians to both rely on and to publish is a strong indicator that the data used in Dr. Betensky's analysis meet and exceed the *Daubert* threshold for scientifically valid method. *Daubert v. Merrell Dow Pharms.*, Inc., 43 F.3d 1311, 1318 (9th Cir. 1995) ("*Daubert II*") (citing *Daubert*, 509 U.S. at 594) ("That the research is accepted for publication in a reputable scientific journal after being subjected to the usual rigors of peer review is a significant indication that it is taken seriously by other scientists, i.e., that it meets at least the minimal criteria of good science.").

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[10] Ex. 29, Andreoli (2014) (comparing "the safety of permanent and retrievable . . . (IVC) filters by reviewing the . . . (MAUDE) database," and concluding that "complications occur with significantly higher frequency with [retrievable IVC filters] compared with [permanent IVC filters]."; same conclusion as Dr. Betensky using more reliable data.); Ex. 30, Angel (2011) (comparing different filters using MAUDE and sales data).

[11] *See, e.g.*, Ex. 32, Dibardino (2009) (MAUDE and other data used to calculate comparative complication rates of devices for treating congenital heart disease, in a study conducted by Harvard Medical School cardiologists and cardiac surgeons); Ex. 33, William (2009) (MAUDE-based "failure rate analysis" of femoral stem fractures); Ex. 34, Thennukonda (2015) (analysis of MAUDE adverse event data regarding dental ultrasonic scalers); Ex. 35, Harth (2009) (analysis of MAUDE data to assess safety of xenograft biologic mesh); Ex. 36, Delaney (2007) (assessment of safety of atrial septal occluding devices using MAUDE, conducted by pediatric cardiologists).

4. Case law supports admissibility of this evidence.

Bard made the same challenge concerning the reliability of the MAUDE data and an expert's analysis based on those data in a prior district court case involving the G2 filter. That court rejected Bard's *Daubert* challenge, and allowed the plaintiff's expert to testify about his statistical analysis and comparisons with the SNF, leaving any challenge to cross-examination. *Tillman v. C.R. Bard, Inc.*, 96 F. Supp. 3d 1307 (M.D. FL 2015). The *Tillman* court was influenced by Bard's use of the same data for a similar analysis. *Id.* at 1332.

Other courts also have allowed experts to rely on MAUDE adverse event data regarding other devices. For example, *Theofanis v. Boston Sci. Corp.*, No. IP-01-752-C-Y/K, 2005 WL 731080 (S.D. Ind. Mar. 16, 2005), concerned the safety of a medical device that consists of a rotating diamond-coated burr maneuvered by a physician through a flexible catheter to a patient's artery. The manufacturer challenged the opinions of the plaintiff's causation expert, who considered several lines of evidence to support his opinions, including review of MAUDE data. *Id.* at *3. The court concluded that the opinions were admissible, in part because the expert relied on multiple lines of evidence. *Id.*; *accord Thompson v. DePuy Orthopaedics, Inc.*, No. 1:13-CV-00602, 2015 WL 7888387, at *5-7 (S.D. Ohio Dec. 4, 2015) (rejecting *Daubert* challenge to expert who reviewed MAUDE data regarding bone cement as part of his product defect analysis).[12]

The cases relied on by Bard, (Mot. at 13-14), are distinguishable because none involved experts who analyzed MAUDE data, let alone an extraction and refinement of those data by the manufacturer itself, with additional verification procedures. First, *Accutane*, *Rider*, *Haggerty*, *Gadolinium-Based Contrast Agents* and *In re Denture Cream*

[12] Some courts have excluded opinions based on MAUDE where the expert did not rely data *in addition to* MAUDE. *See, e.g.*, *Horrillo v. Cook Inc.*, No. 08-60931-CIV, 2014 WL 2708544, at *4 (S.D. Fla. June 6, 2014); *accord Franco v. Boston Scientific Corp.*, 2016 WL 3248505, at *9 (W.D. W.V. June 13 2016) ("Because [the expert's] opinion on post-market vigilance appears to be entirely based on data—or lack thereof—found in the MAUDE database, I find it unreliable."). There are no such problems with Dr. Betensky's opinions.

all involved adverse event reports for pharmaceuticals (i.e., the FAERS database), or case reports—in contrast to MAUDE, which is an FDA adverse event database exclusively for medical devices. Second, all of the aforementioned cases were concerned with the issue of whether the expert testimony proved that the product at issue *caused* the injury; they did not involve a comparison of adverse event reporting rates between devices.

This is an important difference: As the *Tillman* court noted, Bard's cases should be distinguished because "[C]riticisms of the use of [AERS] as a basis for comparing the rate of adverse reactions to drugs . . . are a much less significant issue when evaluating the relative failure rate of medical devices [because] . . . MAUDE . . . is a highly reliable source of information, as a device failure is not attributable to any cause other than a failure of the device." *Tillman* at 1332. In other words, when an IVC filter tilts, fractures, migrates, or perforates, the relationship between the filter and complication is quite obvious. In contrast, an adverse event associated with a medication is often more speculative, i.e., was the injury caused by the medication or by something else? The holding in *Gadolinium* is instructive because while that court did not allow experts to opine that the drug at issue was more likely to cause the disease at issue based on adverse events alone, it ultimately allowed the testimony because there were other indicia of reliability, including use by the FDA: "AERs form only one of numerous bases for their opinions. The same bases and methodology have been used by the [relevant FDA office] in reviewing the relative risk of [the drug at issue], supporting the reliability of Plaintiffs' expert opinions." *In re Gadolinium-Based Contrast Agents Prods. Liab. Litig.*, No. 1:08 GD 50000, 2010 WL 1796334, at *11 (N.D. Ohio May 4, 2010). The Court concluded that the Defendant "is free to cross-examine Plaintiffs' experts regarding the flaws in adverse event reporting." *Id.*

5. Other lines of evidence support Dr. Betensky's conclusions.

Bard's argument for the exclusion of Dr. Betensky's testimony is directed only at her analysis of adverse event reporting rates. Bard does not address at all her opinions related to other lines of evidence, which include an analysis of some of Bard's internal

risk assessment documents and a statistical analysis of Bard's migration resistance bench testing.

Dr. Betensky reviewed a series of Bard documents entitled [redacted] in which Bard made estimates about the failures that would occur with each device. (Ex. 2.) [redacted] (*Id.* at 1.) After evaluating the predictions that Bard made, Dr. Betensky concluded that for failures like perforations and migrations, [redacted] (*Id.* at 2-7.) With some filters, Bard predicted [redacted] (*Id.* at 5, 6.) [redacted] (*Id.* at 7.) Dr. Betensky also considered migration resistance bench testing that compared the Recovery and SNF. (Ex. 1, at 15-16.) In this analysis, Dr. Betensky concluded that [redacted] (*Id.*, p. 16.) Bard does not argue that these conclusions should be excluded.

Moreover, Dr. Betensky's three main analyses are part of a larger picture, and thus cannot be ignored or considered separately, as Bard attempts to do. Several additional lines of evidence provide independent corroboration of Dr. Betensky's analyses, including clinical trials, medical literature, internal documents and bench tests, and engineering analyses.

First, clinical trials and medical literature confirm that Bard's retrievable filters are more likely to fail than other filters. Bard's 61-patient, G2 clinical trial (EVEREST), demonstrated that G2 migrations occurred in 12.2% of filters, caudal migration occurred in 66%, penetration in 21.7%, and tilt in 18.1%. (Ex. 37, at 1452 (Binkert (2009); Ex. 13 ¶¶ 416, 428-29.) Similarly, the 32-patient study of Recovery filter by Dr. Asch, found a

3.7% migration rate and a 3% fracture rate. (*Id.* at 84, ¶ 489, n. 24.)[13] These rates are high when compared with SNF Data (Ex. 38, p. 1) (180-patient, 6-month SNF clinical trial reported no fractures and migrations in 0.8% of patients).[14]

Second, Bard documents indicate that Bard's migration resistance bench tests show retrievable filters performing worse than SNF. Ex. 44 at 973-74; Ex. 45 at 449; Ex. 46 - 47.

Third, engineering analyses confirm that the design of Bard's retrievable filters render them prone to failures. Dr. McMeeking noted that in some conditions the G2 filter will experience [redacted] (Ex. 48, at 9, 10.) He arrived at similar conclusions with respect to the G2x, Eclipse, Meridian, and Denali filters. (*Id.* at 13-25.) Dr. Ritchie conducted microscopic evaluation of fractured filters and concluded that [redacted] (Ex. 49, at 33-34.) In contrast, Dr. McMeeking evaluated the SNF design and concluded that [redacted] (Ex. 50, at 10), and that the SNF had [redacted] (*Id.* at 13-15).

[13] *See also* Ex. 39, Tam (2011) ("5.5-year fracture risk of 40%."); Ex. 40, An (2014) ("estimated 5-year fracture prevalence was 38% (95% confidence interval, 22.9%, 54.8%)"); Ex. 41, Deso (2016) (reporting 38% fractures up to 60 months from implant). Ex. 42, Nicholson (2010) (reported migration rate exceeding 20% in Recovery and G2 filters; fracture rate of 25%); Ex. 43, Hull (2009) ("Recovery filter limb perforation . . . increases over time and is associated with a 21% incidence of filter arm fracture and migration.").

[14] The Everest, Asch, and SNF trials had relatively short follow-up periods that could not capture complications that occurred after the follow-up period. This is relevant because multiple studies have reported increased complication risk with longer implant time.

B. Bard argued in this case that Plaintiffs could redo a similar analysis for which it claimed work-product protection; it would be unfair for Bard to now have this very analysis excluded.

Bard commissioned a consultant, Dr. Lehmann, to do several comparisons between Bard's retrievable filters and the SNF and competitor products—very similar to the analysis at issue here. The report that detailed those analysis was held to be work product, in part, because Bard argued, and the Court held, that Plaintiffs "have full access to all of the data analyzed in Dr. Lehmann's report and . . . their experts can . . . perform the same analysis." (Ex. 51, at 13 (Pre-Trial Order, 2/11/16).) Bard should not now be heard to argue that this very analysis, which if presented from Bard's documents would otherwise be a party-admission, should be excluded because it was conducted by Plaintiff's expert.

C. Bard speculates about adverse events reported for SNF prior to 2000.

Bard's speculation that adverse event reports regarding SNF prior to 2000 have any impact on the analysis fails for multiple reasons. First, as noted above, Bard conducted similar comparisons of adverse event reports for SNF and other filters, limited to data after 2000. Second, Bard refused to produce documents regarding pre-2000 adverse event reports related to the SNF, which prevented Dr. Betensky from considering those data. Third, Bard's argument is based on speculation about the "Weber Effect." Fourth,

Plaintiffs have access to some of these data,[15] and analysis of adverse event reports before 2000 show that they would *strengthen*, not weaken, Dr. Betensky's conclusions.[16]

1. Bard compared SNF adverse event reports with later filters limited to data from 2000 and later.

As demonstrated below, adverse event reports of SNF before 2000 make no difference to Dr. Betensky's analysis. Indeed, back when Bard was concerned with adverse events related to the Recovery filter (2002-2005), Bard conducted similar

[15] Some of the production related to the Recovery and later filters contained hidden rows that were recently discovered to contain adverse event reports relating to the SNF.

[16] The version of the SNF relied on as the predicate for the Recovery Filter was cleared by the FDA on April 28, 1995 (#K944353), so events prior to this date are not relevant to the comparison. (Ex. 13, ¶ 467).

comparisons with data for SNF limited to 2000 and later.[17] As in *Gadolinium-Based Contrast Agents,* independent use of the same method and data is an independent indication of reliability. 2010 WL 1796334, at **2, 6.

2. Bard refused to produce documents relating to SNF.

As noted above, Dr. Betensky had incomplete access to Bard's adverse event data for SNF because Bard refused to produce it. It would be prejudicial for the Court to exclude expert opinions when Bard claimed that the data were not relevant in the first place.

3. Bard's Weber effect claim is speculative.

Bard speculates that the "Weber effect" resulted in an increased reporting of SNF adverse events prior to 2000 that were not considered by Dr. Betensky. As a threshold matter, this is a cross-exam or impeach argument at trial, not an argument for exclusion. And while factually this proposition is demonstrably false (see below), the hypothesis itself is speculation that has not been demonstrated for medical devices and has been disproven for prescription drugs. Hoffman (2014) (Ex. 56) (analysis of 62 drugs showed "most of the modern adverse event reporting… does not follow the pattern described by Weber."). Even if one were to assume that this effect might play a role with prescription drugs, Bard has offered nothing more than speculation that it occurs with medical devices. Even Bard's biostatistics expert, Dr. Thisted, testified that he has not seen any papers discussing the "Weber effect" in the context of medical devices. (Ex. 26 at 123:10-16.) The purported Weber effect argument asserted by Bard itself lacks Rule 702 indicia of reliability.

4. There are few adverse event reports between 1992 and 1999.

With respect to the adverse event reports for the SNF from April 1995 through December, 1999, there are *no* reports of fracture and very few reports of migration,

[17] *See, e.g.*, Ex. 52, at 297 (comparing adverse events for SNF and other filters with Recovery from "2000 to present"); Ex. 53 (chart documenting [redacted]); Ex. 54 (same for time-period [redacted]); Ex. 55 (same, showing data from [redacted]).

perforation, or tilt. Bard produced a spreadsheet that contains a listing of adverse event reports from 1992 through July, 2010. (BPVE-01-01054793.) Dr. Betensky relied on this spreadsheet in forming her opinions (Ex. 1, at 1), but the SNF data before 2000 was hidden in the electronic file by Bard and only recently discovered. When these data were revealed, there are only 13 reports from 1992-2000 that mention migration, (Ex. 57), and 7 of 13 involved deployment issues or stated that migration was not a concern. Similarly, there are only 6 reports of tilt, 4 of which were deployment issues, leaving 2 reports of SNF tilt in an 8-year period. (Ex. 58). Finally, there are 3 perforation reports, 2 of which involved placement, leaving one such report in an 8-year period. (Ex. 59.)[18] Bard did not come forward with any evidence to show that adverse event reports before 2000 had any impact on Dr. Betensky's calculations or results because it could not.

III. CONCLUSION

Dr. Betensky's opinions as to adverse event rates result from a careful and rigorous analysis of Bard's own data that corrects for errors made by Bard employees when they made similar calculations. Because this type of analysis is recommended by the FDA, consistent with and accepted in the field of biostatistics, and available in the published literature, it should not be excluded. Bard has not argued for the exclusion of Dr. Betensky's other opinions, and they should likewise be permitted.

RESPECTFULLY SUBMITTED this 27th day of September 2017.

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[18] Dr. Eisenberg reviewed these pre-2000 data and testified that it would not impact Dr. Betensky's analysis. (Ex. 60 at 266:22-267:2).

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CERTIFICATE OF SERVICE

I hereby certify that on this 27th day of September, 2017, I electronically transmitted the attached document to the Clerk's Office using the CM/ECF System for filing and transmittal of a Notice of Electronic Filing.

/s/ Gay Mennuti